

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM  
POWDER PRODUCTS MARKETING,  
SALES PRACTICES, AND PRODUCTS  
LIABILITY LITIGATION**

**MDL No. 16-2738 (FLW-  
LHG)**

***THIS DOCUMENT RELATES TO ALL  
CASES***

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**PLAINTIFFS' STEERING COMMITTEE'S REPLY MEMORANDUM OF  
LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE EXPERT  
OPINIONS OF DEFENDANTS' MOLECULAR BIOLOGISTS DRS. NEEL,  
SHIH, BOYD, AND BIRRER**

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## I. INTRODUCTION

The Plaintiffs' Steering Committee ("PSC") respectfully submits this reply memorandum of law in support of its motion to exclude the opinions and testimony of Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s (together "J&J") expert molecular biologists Drs. Neel, Shih, Boyd and Birrer.<sup>1</sup>

J&J's opposition<sup>2</sup> to this motion fundamentally misses the point: the opinions of J&J's molecular biology experts are not limited to criticisms of the PSC's witnesses' methods. Instead, these witnesses offer opinions on a supposed absence of biological plausibility – and do so while failing to consider the substantial evidence that Talcum Powder Products contain known carcinogens, including asbestos and fibrous talc, which can cause ovarian cancer.

Having failed to consider this evidence, these witnesses then conclude that there is a lack of evidence of biological plausibility that Talcum Powder Products can cause ovarian cancer. This tautology is unreliable, unhelpful, and should be

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<sup>1</sup> *The Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions of Defendants' Molecular Biologists Drs. Neel, Shih, Boyd and Birrer* (ECF No. 9743-1) (hereinafter "PSC Brief.").

<sup>2</sup> *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude the Opinions of Defendants' Molecular Biologists Drs. Neel, Shih, Boyd and Birrer* (ECF No. 9873) (hereinafter "Defs. Opp.").

excluded – and because it is interwoven throughout these witnesses’ opinions, they should be excluded in their entirety.<sup>3</sup>

In addition, Drs. Shih and Neel are unqualified to offer certain of their opinions. In Dr. Shih’s case, he was unable or failed to address questions on some of the epidemiological analysis in his Fed. R. Civ. P. (“Rule”) 26(b) Report, on the grounds that he lacked expertise in that area, but further testified that his other opinions were based on his epidemiological analysis and review of relevant studies. Dr. Neel’s opinions as to biologic plausibility are inadmissible because he applies the wrong standard to the issue of causation.

Finally, Dr. Shih’s “Study Report” is unreliable because it is incomplete, has no written methodology, no contemporaneous notes, is not peer-reviewed, and because it fails to consider myriad factors that undercut his questionable findings, including but not limited to: (a) the site of origin, rather than site of tumor, of the ovarian cancer tumors included in the study; (b) the underlying medical conditions

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<sup>3</sup> In addition, to the extent that these proffered witnesses criticize the work of PSC expert Dr. Ghassan Saed, their opinions are based on incorrect facts or factual assumptions related to Dr. Saed’s experiments, including dosing, procedures, and maintenance of laboratory notebooks. Further, criticisms directed at Dr. Saed go to the weight of Dr. Saed’s opinion, rather than its admissibility.

The PSC’s arguments related to criticisms of Dr. Saed are addressed in detail in *The Plaintiffs’ Steering Committee’s Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Motion To Exclude Expert Opinion of Ghassan Saed* (ECF No. 9875) (“PSC Saed Opp.”).

of the women from whom the tissue samples were obtained; and (c) medications that the women may have been taking that could have affected the lymphocyte counts relied upon by Dr. Shih. Furthermore, Dr. Shih cites to no literature that supports his underlying hypothesis and does not explain the contradiction of his study results with the extensive literature describing the role of inflammation and oxidative stress in the pathogenesis of ovarian cancer.

## **II. ARGUMENT**

### **A. J&J's Cancer Biology Witnesses Failed To Consider the Composition of Talcum Powder Products**

J&J's experts did not limit their opinions to criticisms of the PSC's experts' methods, as Defense counsel now suggest.<sup>4</sup> Instead, J&J's experts offer detailed but materially incomplete opinions about the biological plausibility of Talcum Powder Products causing ovarian cancer and weave it into the guise of criticizing the methods of the PSC's experts.

While J&J's expert witnesses may know a lot about the molecular-level genetics of cancer, that does not mean their testimony is either reliable or helpful. Their discussions of the epidemiological literature are incomplete and unavailing in light of the material deficits in their understanding of the talcum powder/ovarian cancer specific epidemiologic literature as well as general epidemiological concepts

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<sup>4</sup> Defs. Opp. at 12-15.

(i.e. confidence intervals). Moreover, their opinions are uninformed by any knowledge, expertise, or even basic awareness of the constituents of Talcum Powder Products and whether those constituents can cause ovarian cancer.

J&J's witnesses were able to offer opinions on the "non-plausibility" of talcum powder causing ovarian cancer only by failing to consider the constituents of the Talcum Powder Products. It calls to mind a clarifying point made by the Chief Justice in the context of a patent case:

CHIEF JUSTICE ROBERTS: Who do you get to be an expert to tell you something's not obvious –

MR. GOLDSTEIN: You get –

CHIEF JUSTICE ROBERTS: I mean, the least insightful person you can find? (Laughter.)<sup>5</sup>

This is exactly what J&J has done in this case by not asking its experts to consider the constituents of the Talcum Powder Products. No reasonable scientist addressing this issue could fail to find it biologically plausible that, for example, asbestos – a known carcinogen – causes cancer.

Putting their experts' heads in the sand is a bold move, and that is what J&J has effectively done. When asked about the carcinogenic constituents of Talcum Powder Products, J&J's proffered experts declaimed any knowledge of what those

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<sup>5</sup> 11/28/06 Oral Argument Tr. from *KSR Int'l Co v. Teleflex, Inc.*, 550 U.S. 398 (2007), attached hereto as Exhibit 1, at 49:17-22.

constituents are or might even be, and in any circumstance whether they can cause cancer. Instead, they uniformly bootstrapped a cursory review of the epidemiology into an assertion of non-plausibility.

The result is unreliable. Epidemiological studies, by their nature, do not assess the molecular events of carcinogenesis; they report what is observed in large groups of humans. Here the molecular-level analysis emphasized by J&J requires at least some understanding of what is in Talcum Powder Products or whether those components can cause cancer.

While J&J's experts may have expertise in molecular biology, in order for them to offer a reliable opinion on what is at issue in this case, they must know the composition of the substance at issue. Without knowing the substance (constituents of Talcum Powder Products) they cannot offer a reliable opinion. Likewise, the same experts cannot decree a lack of expertise in epidemiology but rely upon their epidemiologic review of relevant studies as the basis for their opinions. Without filling these gaps, their opinions are infected by a fatal flaw that precludes admission of their testimony as to biological plausibility – and that plausibility issue is so interwoven with their criticisms of the PSC's experts' methodologies that their entire opinions should be excluded.

J&J further suggests, “[t]his all-star team of experts evaluated plaintiffs’ experts’ biological plausibility hypotheses and unanimously concluded that these



hypotheses lack scientific support and that plaintiffs' experts' methods are unreliable.”<sup>6</sup> However, J&J fails to share with this Court that J&J's proffered expert, Dr. Jeff Boyd, “the founding director of the Center for Genomic Medicine at the Miami Cancer Institute (who) focuses his research on the genetics and molecular genetics of gynecologic and breast cancers,” coauthored, in 2008, a peer-reviewed, conference report following a 2007 conference on ovarian cancer which found:<sup>7</sup>

[A] combination of demographic, reproductive and environmental risk factors might be used to develop a model that would more accurately predict risk. One preliminary algorithm using seven risk factors (age over 45; ***long-term genital talc use***; family history of ovarian cancer or early onset breast cancer; Jewish ethnicity; no oral contraceptive (OC) use; no livebirths; no breastfeeding; no tubal ligation) showed that women with six to seven of these events have an OR of 7.59.

Importantly, ***J&J's own expert witness*** authored a peer reviewed paper showing among other risk factors, that long-term genital talc use increased ovarian cancer risk by 659%. J&J would now have this Court believe that it is not even “plausible” that regular genital talc use increases risk of ovarian cancer. It is an absurd position that belies the evidence.

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<sup>6</sup> Defs. Opp. at 1.

<sup>7</sup> See Ashworth A, Balkwill F, Bast RC, Berek JS, Kaye A, Boyd JA, Mills G, Weinstein JN, Woolley K, Workman P. Opportunities and challenges in ovarian cancer research, a perspective from the 11<sup>th</sup> Ovarian Cancer Action/HTTMT Forum, Lake Como, March 2007. Gynecol Oncol. 2008 Mar; 108(3):652-7. Epub 2007 Dec 21. (emphasis added), attached hereto as Exhibit 2.

**B. Dr. Shih Avoided Questioning by Testifying He Was Not an Expert in Epidemiology**

As to the PSC's criticisms of J&J expert Dr. Shih, J&J again misses the point. In general, medical doctors (including pathologists) may well be equipped to offer opinions based in part on epidemiology.<sup>8</sup> But Dr. Shih's opinion is inadmissible because he is unfamiliar with basic epidemiological concepts and refused to answer questions on epidemiology at his deposition *on the basis that he is not an expert in that field*, yet his opinions are founded on an epidemiologic evaluation of available literature.

As set forth in detail in the PSC's opening brief on this issue, Dr. Shih testified that *"my opinion is based on my literature search about epidemiology."*<sup>9</sup> Dr. Shih's report is based upon and includes a discussion of the confidence intervals ("CIs") of several epidemiological studies. When asked about how he interprets CIs at his deposition, Dr. Shih's testimony was, "I'm a cancer biologist and a gynecology pathologist. I review those articles that is relevant and important and – and related. *I am not epidemiology expert. You can – you should defer those question to them.*"<sup>10</sup>

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<sup>8</sup> See Def. Opp. at 19-22.

<sup>9</sup> PSC Brief at 34-37 (emphasis in original).

<sup>10</sup> Shih Dep. at 67:10-68:1 (emphasis added).

Arguably, even if he is one “of the world’s leading cancer researchers,”<sup>11</sup> Dr. Shih needs to be held accountable for his testimonial evidence at deposition. Having disavowed expertise in epidemiology at his deposition in order to avoid questioning on the aspects of his Rule 26(b) report addressing the subject, J&J cannot now seek to undo Dr. Shih’s sworn testimony.<sup>12</sup> As outlined in his expert report, Dr. Shih’s opinions regarding talcum powder are founded, in part, upon his review of epidemiologic literature. His own testimony underscores his lack of knowledge and inability to apply epidemiologic expertise and should invalidate any epidemiologic opinions put forward in his expert report or deposition.

J&J implies that there is a double standard at play by virtue of the PSC’s offering of Dr. Kane’s epidemiologically-based testimony, while seeking to exclude that of fellow pathologist, Dr. Shih. There is only one standard here. The difference between their testimony is self-evident: Dr. Kane did not disclaim expertise in epidemiology at her deposition, nor did she avoid questioning about the epidemiology in her report.

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<sup>11</sup> Defs. Opp. at 20.

<sup>12</sup> In addition, as discussed in detail by the PSC in its opening brief, Dr. Shih was unable or unwilling to discuss the Bradford Hill aspects of causation. *See* PSC Brief at 34-37.

Further, as previously discussed in detail,<sup>13</sup> Dr. Shih testified that his entire opinion was so strongly held, in part based on his epidemiological review, that even differing experimental results in his laboratory work would not change his mind.<sup>14</sup> Because epidemiology undergirds his opinions, and because Dr. Shih could not, or would not, answer questions about basic epidemiological concepts. Dr. Shih's entire opinion is suspect and should be excluded.

### C. **Dr. Neel's Opinion Is Unreliable Because He Applied the Wrong Methodology**

J&J's response with respect to Dr. Neel also misses the point. First, Dr. Neel's opinion is based to a significant extent on his methodological assessment of epidemiological studies. His flawed methodology is disqualifying and renders his opinions unreliable . . .<sup>15</sup>

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<sup>13</sup> PSC Brief at 37-39.

<sup>14</sup> "But again, *my opinion will not change, even [if] there is a different result in my official publications. My opinion is based on my literature search about epidemiology*, chronic inflammation, carcinogenesis, molecular genetics, and my 20 years of experience as a scientist and pathologist." Shih Dep. at 112:7-12 (emphasis added).

<sup>15</sup> See Neel Report, at, e.g., 12 ("*epidemiological reports*, that treat 'ovarian cancer' as a single entity, should, in my opinion, be viewed with skepticism"), 14-16 (discussing "the numerous *epidemiological studies* on the topic of talc and ovarian cancer. . . In my opinion, the studies cited by this report are weak and unconvincing" and discussing "*multiple epidemiological studies*" in detail), 17 ("unreliability of conclusions based solely on *epidemiological studies* that rely entirely on self-reporting of talc exposure"), 26 (*criticizing "Dr. Zelikoff, who points to epidemiological data from Gates et al. . . ."*), 27 ("As with any weak *epidemiologic association . . .*", "the *epidemiologic data* fail to show a compelling dose-response

Secondly, even if Dr. Neel had flatly stated that he is qualified as an expert in epidemiology, the relevant test is whether he actually *is* qualified, not whether he *says* that he is.<sup>16</sup> And here, the qualification issue blends into the issue of the opinion's reliability and fitness under *Daubert*, because Dr. Neel used the wrong methodological standard to assess causation.

Dr. Neel should have performed a Bradford Hill analysis. Instead, as set forth in detail in the PSC Brief at 31-33, Dr. Neel applied his own unique criteria, which is inconsistent with and ignores Bradford Hill. In contrast, *J&J's own witness*, Dr. Merlo states correctly, that “*none* [of Bradford Hill's aspects of causation] *is required or absolutely essential*,”<sup>17</sup> yet in Dr. Neel's opinion, biological plausibility *was* “essential.”<sup>18</sup> Dr. Neel testified about the heightened standard he believes should be applied to a molecular analysis, rather than the mere plausibility that is actually required:

Q. Using a Bradford Hill framework, does evidence for plausibility need to be strong?

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relationship”), and 28 (discussing “*epidemiological research*” and “evidence from the *epidemiological literature*”) (emphases added).

<sup>16</sup> As set forth in the PSC Brief at 29-33, Dr. Neel testified that he is not an epidemiology expert and that he has never previously conducted a Bradford Hill analysis.

<sup>17</sup> Merlo Report at 30 (emphasis added); *accord*, Hill article, at 299. See PSC Brief at 31-32, esp. at fn. 55-56, and at 33, fn. 60, for a more detailed discussion.

<sup>18</sup> Neel Dep. at 149:1.

- A. In my opinion, to attribute causation of any agent to the initiation of any malignancy, the evidence has to be ***strong, convincing, and definitive***, yes.<sup>19</sup>

Here, Dr. Neel radically departs from Bradford Hill's aspects of causation. Accordingly, Dr. Neel's opinions regarding causation should be excluded in their entirety.

**D. Dr. Shih's Work Is Unreliable Because of Significant Methodological Errors and Weaknesses**<sup>20</sup>

In response to the PSC's *Daubert* challenge, J&J notes that Dr. Shih detected chronic inflammation in all of the cases of ovarian carcinoma, but in none of the precancerous lesions or samples of healthy tissue he examined.<sup>21</sup> These observations supposedly provide evidence that the inflammation associated with ovarian cancer arises in carcinomas ***after*** their development rather than in cancer ***precursors***, which J&J suggests "refut[es] the hypothesis that chronic inflammation is the cause of ovarian cancer." *Id.*

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<sup>19</sup> *Id.* at 159:8-14 (emphasis added).

<sup>20</sup> The methodological weaknesses include the failure to account for the women's underlying medical conditions, the medications which they may have been on which may have affected the lymphocyte counts he relies upon, and the fact that some 25% of the precursor cells may have been 'metastatic' cells which wouldn't have shown the 'inflammation' around them that Dr. Shih is relying upon as the basis for his opinions.

<sup>21</sup> Defs. Opp. at 9.

The PSC's experts disagree with the findings of Dr. Shih's "study" and their meaning in relation to inflammation and the development of epithelial ovarian cancer. There are numerous methodological flaws in Dr. Shih's study that render it and any opinions based upon the study unreliable and unhelpful to a jury. As noted in detail in the PSC's *Daubert* challenge,<sup>22</sup> any evidence or testimony regarding Dr. Shih's study should be excluded because: 1) the study is not final or complete; 2) the study has no written protocol; 3) no contemporaneous notes were taken during the study, essentially making the results not reproducible (a hallmark of reliability); and 4) it is not peer-reviewed or published.

J&J attempts to rehabilitate Dr. Shih's testimony regarding his Study Report as being a "work in progress" or a "draft," by stating that "Dr. Shih's report is sufficiently final to satisfy the reliability requirements of Daubert" and that further, "In keeping with this principle, it is acceptable . . . to rely on a study that is subject to future refinement and development."<sup>23</sup> Dr. Shih describes his Study Report as an "interim report" and "at this moment, we don't – I'm sorry, I don't know whether this will be a single long paper just reporting this finding or in combination with other finding as multiple reports or a single one publication report. I have no idea

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<sup>22</sup> PSC Brief at 46-50.

<sup>23</sup> Defs. Opp. at 32.

yet.” He further hedged with “...the data I have, but when you wrap up a study, you have other ingredients, like introduction, methodologies, result, discussion. This is not full report as a publication. I mean a full report meaning its publication. Okay. But this is a full result I have at this moment.”<sup>24</sup>

However, *every* interim result is a full result as of the time it is taken; the issue is whether that “result” is a final one under Rule 26(b). Without the requisite finality, the PSC was unable to fully question Dr. Shih and explore his study methods, findings and opinions.

A final limitation inherent in Dr. Shih’s Interim Report, but not discussed by J&J, is the fact that he did not have access to, nor did he review, the underlying medical records associated with each woman’s histopathology slide. This failure prevented Dr. Shih from ascertaining if any of the women’s underlying medical condition (i.e., pelvic inflammatory disease, endometriosis, and/or previous tubal surgery) or medications that may have affected the presence of histologic evidence of inflammation,

For these reasons, Dr. Shih’s study and any of Dr. Shih’s opinions based in whole or in part on this flawed interim study are unreliable and unhelpful to the jury and should be excluded.

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<sup>24</sup> Shih Dep. 100:9-23.



### III. CONCLUSION

For these reasons, the Court should grant the PSC's motion to exclude the opinions and expert reports of Drs. Shih, Neel, Boyd, and Birrer, including Dr. Shih's interim Study Report and his opinions based thereon.

Respectfully submitted,

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